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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,401	03/30/2006	Paul Tardi	532552001000	5586
25225 7590 08/04/2009 MORRISON & FOERSTER LLP			EXAMINER	
12531 HIGH B	LUFF DRIVE	MAEWALL, SNIGDHA		
SUITE 100 SAN DIEGO, CA 92130-2040			ART UNIT	PAPER NUMBER
			1612	
			MAIL DATE	DELIVERY MODE
			08/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
Office Action Summers	10/551,401	TARDI ET AL.				
Office Action Summary	Examiner	Art Unit				
	Snigdha Maewall	1612				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠ Responsive to communication(s) filed on <u>30 Ma</u>	arch 2006					
· <u> </u>	, 					
•	/ 					
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>1-41</u> is/are pending in the application.	4) Claim(s) 1-41 is/are pending in the application.					
4a) Of the above claim(s) is/are withdraw	4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.						
6) Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.	•					
8) Claim(s) <u>1-41</u> are subject to restriction and/or e	election requirement					
	nootion roquiromont.					
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	priority under 35 LLS C & 119(a)	(d) or (f)				
a) ☐ All b) ☐ Some * c) ☐ None of:	12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
·- <u>-</u> ·-						
	1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)						
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application						
3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application 6) Other:						

DETAILED ACTION

Claims **1-41** are pending in this application.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- Group I, claim(s) 1-20 and 30-33, drawn to a composition comprising delivery vehicles with specific diameter in the range of 50-300nm
- Group II, claim(s) 21-26 drawn to a composition with delivery vehicles and drug resistance modulators with no specific diameter
- Group III, claim(s) 27 drawn to a method to impart drug sensitivity to a subject...
- Group IV, claim(s) 28 and 34-37 drawn to a method to impart to a subject by administering a drug sensitivity composition...
- Group V, claim(s) 29 and 38-41 drawn to a method of administration to treat....

The inventions listed as Groups I to V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups I to group V do not have a common technical feature that distinguishes the claims over the prior art. The common technical feature found in all groups is a delivery vehicle with therapeutic agent and drug resistance modulator. Prior art by VAAGE et al. teach therapy of mouse mammary carcinomas with vincristfine and doxorubicin encapsulated in sterically stabilized liposomes. Int. J. Cancer. 1993. Vol. 54, pages 959- 964, entire publication, presented in IDS.

Thus, the technical feature is lacking unity since a composition with delivery vehicles is not a technical feature that defines a contribution over a prior art as evidenced by Vaage et al.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- 1) drugs
- 2) drug resistance modulators
- 3) delivery vehicles

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The single technical feature among the species are liposomes, and which are taught in prior art cited above. If it can be shown that one species is not novel over the prior art, then unity of invention is lacking. In instant case, this is evidenced by the cited prior art wherein the prior art discloses a therapy of mouse mammary carcinomas with vincristfine and doxorubicin encapsulated in sterically stabilized liposomes. Int. J. Cancer. 1993. Vol. 54, pages 959-964, entire publication (record in IDS).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double

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patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/ Examiner, Art Unit 1612 /Gollamudi S Kishore/ Primary Examiner, Art Unit 1612 Application/Control Number: 10/551,401

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